



**Standard  
Process®**

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December 15, 1999



The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) The members of the B complex family of vitamins work collectively to metabolize fats, proteins, and carbohydrates. They are each singularly responsible for many important physiological processes concerned with both physical and mental health and wellbeing. Thiamin, for example, is responsible for breaking down carbohydrates into simple sugar, which the body then oxidizes to produce energy for all the cells. Niacin is a co-enzyme essential for cell respiration, protein and carbohydrate metabolism, and lipid synthesis. Vitamin B6 performs many important regulatory tasks inside the body, but its main responsibility is to break down and synthesize amino acids. Vitamin B6 regulates and maintains the delicate fluid balance throughout the body, and assists in nervous and musculo-skeletal system functions by upholding a proper sodium and potassium balance at the cellular level.
- (2) Supports immune and nervous system function.
- (3) Vitamin B6 enhances immune efficiency, aids in antibody production and promotes red cell formation. Thiamin improves mental attitude and increases learning efficiency. The B vitamins are thought to be the single most important factor in maintaining the health of nerves.
- (4) Influences cellular health and metabolic efficiency.
- (5) Thiamin provides energy for cells by breaking down carbohydrates into simple sugar. Niacin is necessary to maintain healthy skin while working to metabolize carbohydrates, fats, and proteins. Vitamin B6 is required to synthesize the important

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nucleic acids RNA and DNA. Vitamin B6 assists in the production of hydrochloric acid necessary for digestion and the proper absorption of fats and proteins.

- (6) Maintains a healthy circulatory system.
- (7) The heart muscle requires thiamin to keep it strong and pumping efficiently. Niacin and vitamin B6 each have the ability to help maintain healthy cholesterol levels in the blood and improve circulation. Vitamin B6 also helps maintain healthy homocysteine levels.
- (8) The liver is a great storehouse of vitamins and minerals and is utilized because it is not only a rich source of nutrients, but also provides nutritional "stimulative" support to the liver.
- (9) Whole desiccated animal tissue proteins provide nutrients and support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine liver, nutritional yeast, porcine duodenum, beet (root), carrot (root), dried beet (root) juice, choline bitartrate, rice (bran) extract, defatted wheat (germ), bovine adrenal, oat flour, soybean lecithin, mixed tocopherols, ascorbic acid, manganese lactate, inositol, and riboflavin. Other ingredients include honey, niacinamide, potassium para-aminobenzoate, calcium stearate, arabic gum, cocarboxylase, and pyridoxine hydrochloride. The name of the product is Cataplex® B.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.